

From: [Jay Field](#)
To: [Eric Blischke/R10/USEPA/US@EPA](#)
Subject: Re: bioassay interpretation information and meeting
Date: 06/18/2009 12:29 PM

it's more than just using another software package. it means selecting what distribution/percentile approach. using a more sophisticated software package involves making choices far beyond the straightforward approach that MacDonald recommended. what they have done complicates this question, is done without any review, after guidance was provided. my recommendation:

- 1) use control normalization (test result divided by control results).
 - 2) use the 4 bins based on 10% of RE
 - 3) if you allow them to develop the RE's using specialized software, they should provide a memo describing the percentile approach they selected and the rationale for selection. this memo should be reviewed before they proceed.
 - 4) evaluate toxicity significance determination for power of test (any non-significant test result with low power should be included in the effect level based on the RE
- Jay

Blischke.Eric@epamail.epa.gov wrote:

Agree that standard control normalization techniques should be used.
The RE values we provided were essentially direction to the LWG.
However, if they used a different software package to get a slightly different RE value, I can live with that. However, as I stated in my email, we need to be using 10% of the RE and separating the results into four instead of 3 bins.

Eric

Jay Field <Jay.Field@noaa.gov>	
To	Eric
Blischke/R10/USEPA/US@EPA	
06/18/2009 12:04	
cc	Robert Gensemer <rgensemer@parametrix.com> ,
PM	Shephard/R10/USEPA/US@EPA,
Burt	Goulet/R10/USEPA/US@EPA,
Joe	Neely
Robert	Benjamin Shorr <Benjamin.Shorr@noaa.gov>
<Robert.Neely@noaa.gov> ,	
Subject	Re: bioassay interpretation information and meeting

Eric,
I will be on the call but have not had time to look at the information from LWG.
It was my understanding that you provided specific thresholds to LWG in table RE-2 in your March 31 memo or was that meant only as an example?
The approach of subtracting control from test results is not a standard approach (we have commented on that before) and in our opinion standard control-normalization (test/control) should be used.
Jay

Blischke.Eric@epamail.epa.gov wrote:

This is a good summary. My take on this is:

1) It should be acceptable for the LWG to use the @risk software (or some other software) to develop the 5th percentile even if the

software

package they used resulted in a less conservative reference envelope value.
2) The LWG should be using 10% of the RE value not the absolute 10%.
Although the language in the Calcasieu example may be ambiguous,

actual

calculations used in the Calcasieu are not and should be followed.
3) We should be categorizing the results into the four bins that we specified in our March 31st direction (adjusted of course for the

@risk

generated RE value and using the 10% of the RE criteria).
4) We should also make sure that the significant difference from control determination was done appropriately.

Does everyone feel comfortable talking with the LWG?

Eric

Robert Gensemer

<rgensemer@param

etrix.com>

To

Blischke/R10/USEPA/US@EPA,

Eric

06/18/2009 10:59
Shephard/R10/USEPA/US@EPA,

Burt

AM
["jay.field@noaa.gov"](mailto:jay.field@noaa.gov)

[<jay.field@noaa.gov>](mailto:jay.field@noaa.gov), Joe

Goulet/R10/USEPA/US@EPA

cc

Subject

interpretation

RE: bioassay

meeting

information and

Joe and I just talked and thought a few initial observations would be helpful to all know in advance of our 1pm call in case all of you

don't

get a chance to look at this in much detail:
- Their methods for deriving the 5th percentile were, as expected,

quite

different than ours. They used @risk instead of the Excel PERCENTILE function. That in itself is probably OK, but ironically, ALL of the resulting RE values end up being lower (i.e., less conservative) than ours.
- They set up their toxicity levels based on subtracting (or adding, depending on how you do things) an absolute 10% from the RE value, NOT 10% OF the RE value, as we directed and as was done in Calcasieu.
- They did not break things down into four toxicity levels as we did

(no

effect, minor effect, moderate effect, severe effect), but instead

only

used three (level 1, level 2, level 3, with level 1 being the RE

value,

so would be a no effects threshold). Not sure how big a difference

this

is, but I think just means that the yellow dots on their figure (level 2s) would include all the sites we called level 1 AND level 2 in our

GIS

layer. Their level 3s would be the same as our level 3s,
and their

level

ls would be the same as our "non-toxic" in our GIS
layer.

Will keep digging, but this seems to be the big
differences.

-Bob

From: Blischke.Eric@epamail.epa.gov [
<mailto:Blischke.Eric@epamail.epa.gov>]
Sent: Thursday, June 18, 2009 9:54 AM
To: Shephard.Burt@epamail.epa.gov; Robert Gensemer;

jay.field@noaa.gov;

Goulet.Joe@epamail.epa.gov

Subject: Fw: bioassay interpretation information and
meeting

Apparently there were some problems with me receiving
this email even
though it was sent yesterday at 2:00 pm. In any event,
here is the
information. If possible, I would still like to have
the call.

Eric

----- Forwarded by Eric Blischke/R10/USEPA/US on
06/18/2009 09:51 AM

John Toll

<JohnT@win

dwardenv.c

om>

To

Eric Blischke/R10/USEPA/US@EPA, Chip

Humphrey/R10/USEPA/US@EPA

06/18/2009

cc

09:47 AM
Jennifer

Helle Andersen [<HelleA@windwardenv.com>](mailto:HelleA@windwardenv.com),

Keith Pine

Woronets [<jworonets@anchoragea.com>](mailto:jworonets@anchoragea.com),

[<kpine@anchoragea.com>](mailto:kpine@anchoragea.com), Lucinda Tear

Musgrove

[<LucindaT@windwardenv.com>](mailto:LucindaT@windwardenv.com), Nancy

[<NancyM@windwardenv.com>](mailto:NancyM@windwardenv.com), Bob Wyatt

[<rjw@nwnatural.com>](mailto:rjw@nwnatural.com)

Subject

and meeting

RE: bioassay interpretation information

RETRANSMITTAL excluding ZIP file containing GIS layers.
Eric, please
confirm receipt. John

Hi Eric. Attached please find materials you requested
to receive in
advance of tomorrow's bioassay check-in. The attached
materials

include

the GIS layers for the LWG's bioassay hit classification
(zipped in

the

file hit layers.zip), a PDF map of the LWG's bioassay
hit
classification results, and the spreadsheet showing how
we obtained

the

reference envelope values (REVs) and hit thresholds for
the four
bioassay endpoints. Please let me know if you have
questions or need
additional information. John

John Toll, Ph.D.
Partner
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From: Blischke.Eric@epamail.epa.gov [
<mailto:Blischke.Eric@epamail.epa.gov>]
Sent: Monday, June 15, 2009 1:57 PM
To: John Toll; Humphrey.Chip@epamail.epa.gov
Cc: Helle Andersen; Jennifer Woronets; Keith Pine;
Lucinda Tear; Nancy
Musgrove; Bob Wyatt
Subject: Re: bioassay interpretation information and
meeting

John, attached is a spreadsheet that shows the data we
have for the

293

tox samples and the calculated effect levels, which were
based on the
values for the 4 endpoints in table RE-2. The
management meeting has
been scheduled for 9:00 am on Friday. Right now, I am
confirming that
Thursday afternoon will work. If we are going to meet
on Thursday, It
is critical that we receive the requested materials by
COB Wednesday.

Eric

John Toll

<JohnT@win

dwardenv.c

om>

06/12/2009

To

05:12 PM

Eric Blischke/R10/USEPA/US@EPA

cc

Pine

Bob Wyatt rjw@wnnatural.com, Keith

kpine@anchorgea.com, Jennifer Woronets

Andersen

jworonets@anchorgea.com, Helle

HelleA@windwardenv.com, Lucinda Tear

Musgrove

LucindaT@windwardenv.com, Nancy

NancyM@windwardenv.com

Subject

meeting

bioassay interpretation information and

Hi Eric. I just got done talking with Bob and we're not going to be able to give you the information you've asked for (the bioassay hit classification GIS layer and the spreadsheet showing how we got the

hit

thresholds) until after the LWG's Exec meeting next Wednesday morning. Because we can't get you the information until then, we'd like to reschedule the meeting for either next Thursday afternoon (anytime

after

1:00), or possibly next Friday before the managers' meeting (although Bob wasn't sure about when the managers' meeting is going to be so he wasn't sure that Friday would work). John

John Toll, Ph.D.
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